

CERTIFICATE OF ANALYSIS

| 品名: 盐酸土霉素 PRODUCT: OXYTETRACYCLINE HYDROCHLORIDE | 报告编号: 210176 REPORT NO | | |
|--|--|----------------------------|------------|
| 批号: 210408 BATCH NO | 净重: 25kg/DRUM NET WEIGHT | | |
| 数量: 1000 kg QUANTITY | 包装数量: 40 DRUMS NUMBER OF PACKAGE | | |
| 根据: ACCORDING TO | 英国 2017 版/ BP2017 | | |
| | 生产日期: 2021.04.07 DATE OF MANUFACTURE | | |
| | 报告日期: 2021.04.08 DATE OF ANALYSIS | | |
| | 有效期: 2025.04.06 EXPIRY DATE | | |
| 检验项目 TESTS | 标准 SPECIFICATION | 结论 RESULTS | 单位 UNIT |
| 性状 Description | 黄色结晶粉末 Yellow crystalline powder | 符合 Complies | --- |
| 鉴别 Identification | 依据 BP2017 According to BP2017 | 符合 Complies | --- |
| pH 值 pH Value | 2.3~2.9 Between 2.3 and 2.9 | <u>2.4</u> | --- |
| 吸收系数 Absorbance(353nm,pH2.0) | 270~290 Between 270 and 290 | <u>272</u> | --- |
| 比旋度 Specific optical Rotation | -188 ° ~ -200 ° Between -188 ° and -200 ° | <u>-191 °</u> | * |
| 重金属 Heavy metals | 不得大于 50 Not more than 50 | 符合 Complies | ppm |
| 杂质吸收度 Light absorbing Impurities | A(0.2%,1cm,430nm)<0.50 Absorbance at 430nm shall Not be more than 0.50 A(1%,1cm,490nm)<0.20 Absorbance at 490nm shall Not be more than 0.20 | <u>0.11</u> <u>0.10</u> | |
| 相关物质 Related substances | 杂峰含量应符合规定 content of impurity peak meets the requirements | 符合 Complies | |
| 炽灼残渣 Sulfated ash | 不得大于 0.5% Not more than 0.5% | <u>0.08%</u> | W/w |
| 水份 Water | 不得大于 2.0% Not more than 2.0% | <u>1.2%</u> | W/w |
| 含量(HPLC) HPLC Assay | 95.0%~102.0% (按无水物计) Between 95.0% and 102.0% Anhydrous substance | 96.5% | W/w |
| 结论: 本品符合英国药典 2017 版之规定 THIS PRODUCT FULFILLS BP2017 | | | |